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Merck & Co., Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK & CO., INC. Plaintiff, v. APOTEX, INC. and APOTEX CORPORATION Defendants.	DOCUMENT ELECTRONICALLY FILED Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

Plaintiff Merck & Co., Inc., for its complaint against Defendants Apotex, Inc. and Apotex Corporation, hereby alleges as follows:

THE PARTIES

1. Plaintiff Merck & Co., Inc. ("Merck") is a corporation incorporated and existing under the laws of the State of Delaware, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Upon information and belief, Defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business in Weston, Ontario, Canada.

3. Upon information and belief, Defendant Apotex Corporation ("Apotex Corp.") is a corporation organized and existing under the laws of Delaware, having its principal place of business in Weston, Florida.

4. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex, Inc. and the acts of Apotex, Inc. complained of herein were aided and abetted by and done with the cooperation, participation, and assistance of Apotex Corp.

5. Apotex Corp. and Apotex, Inc. are hereinafter collectively referred to as "Apotex".

JURISDICTION AND VENUE

6. This action arises under the Patent laws of the United States and the Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, Apotex sells various products and conducts business throughout the United States, including within this District.

8. Upon information and belief, Apotex will sell the generic product accused of infringement in this Complaint through Apotex Corp., throughout the United States, including within this District.

9. This Court has personal jurisdiction over Apotex, and venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d), and 1400(b).

CLAIM FOR RELIEF

10. Merck filed New Drug Application ("NDA") No. 20-869, by which the United States Food & Drug Administration ("USFDA") first granted approval for an ophthalmic solution including the active ingredients dorzolamide in combination with timolol. The combination solution described in Merck's NDA is prescribed for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma who are insufficiently responsive to beta-blockers. Merck sells this solution in the United States under the trademark COSOPT®. Open-angle glaucoma is a disorder characterized by elevated intraocular pressure (pressure within the eyeball) which can lead to damage to the optic nerve and loss of vision, and is one of the leading causes of irreversible blindness in the United States.

11. Merck is the owner of United States Patent No. 4,797,413 ("the '413 patent"), entitled "Thieno Thiopyran Sulfonamide Derivatives, Pharmaceutical Compositions and Use," which was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on January 10, 1989. The USPTO confirmed the patentability of all the claims of the '413 patent in a reexamination certificate issued November 24, 1992.

12. The '413 patent discloses and claims certain compounds, including dorzolamide, an active ingredient in COSOPT®, and certain ophthalmic formulations for the treatment of ocular hypertension and methods of treating ocular hypertension.

13. The '413 patent was granted, by the USPTO, an extension of patent term of 1,233 days, pursuant to 35 U.S.C. § 156 to restore a portion of the loss of effective patent protection resulting from time consumed by the regulatory review period leading to the USFDA's approval of dorzolamide.

14. A copy of the '413 patent is attached as Exhibit A.

15. Upon information and belief, Apotex filed in the USFDA an Abbreviated New Drug Application ("ANDA") including a certification with respect to the '413 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell "Dorzolamide Hydrochloride/Timolol Maleate Ophthalmic Solution, 2%/0.5%" prior to the expiration of that patent (referred to herein as "the Apotex ANDA product").

16. On or about October 23, 2006, Apotex mailed a notice to Merck in which Apotex represented that it had filed an ANDA, No. 78-201, for "Dorzolamide Hydrochloride And Timolol Maleate Ophthalmic Solution, 2%/0.5%," including the certification with respect to that patent.

17. Because Apotex seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug claimed in the '413 patent before its expiration, Apotex has infringed the '413 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

18. The Apotex ANDA product (and the use indicated in the ANDA) fall within the scope of one or more of the claims of the '413 patent, including, without limitation, claims 1, 2, 4, 6, 7, 8, 9, 10, 11, 12 and 13 (the "asserted claims").

19. The asserted claims of the '413 patent satisfy the requirements for patentability set forth in Title 35 U.S.C., including §§ 101, 102, 103 and 112 thereof.

20. As of April 21, 1997, when the USPTO granted the Certificate Extending Patent Term Under 35 U.S.C. § 156, the '413 patent satisfied the requirements set forth in the provisions of 35 U.S.C. § 156 for an extension of patent term.

21. Pursuant to 21 U.S.C. § 355a, Merck obtained and provided information on the benefits of dorzolamide in a pediatric patient population and, as a result, the earliest date on which the USFDA may approve Apotex's ANDA is a date that is not earlier than six months after the expiration of the '413 patent.

22. Merck is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Apotex's ANDA be a date that is not earlier than six months following the date of expiration of the '413 patent, and any later expiration of exclusivity for the '413 patent to which Merck is or becomes entitled.

23. Upon information and belief, Apotex was aware of the existence of the '413 patent and, upon information and belief, was aware that the filing of its ANDA and certification with respect to the '413 patent constituted an act of infringement of that patent.

24. Apotex's statement of the factual and legal bases for its opinion regarding the invalidity, unenforceability and non-infringement of the '413 patent is devoid of an objective good faith basis in either the facts or the law.

25. This case is an exceptional one, and Merck is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that Defendants have infringed the '413 patent by submitting the aforesaid ANDA;

(b) A judgment declaring that this case is exceptional, and that Plaintiff is entitled to its reasonable attorney fees pursuant to 35 U.S.C. § 285.

(c) To the extent Defendants have committed any acts with respect to the subject matter claimed in the '413 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiff be awarded damages for such acts, which this Court should treble pursuant to 35 U.S.C. § 284;

(d) A permanent injunction be issued pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Apotex, its officers, agents, attorneys, and employees, and those acting in privity or concert with them from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compounds as claimed in the '413 patent;

(e) An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 78-201 be a date that is not earlier than six months following the date of expiration of the '413 patent, or any later expiration of exclusivity for the '413 patent to which Plaintiff is or becomes entitled; and

(f) Such other relief as this Court may deem proper.

Dated: December 4, 2006

s/Melissa L. Klipp

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the within action is not the subject of any other action pending in any Court, or of any pending arbitration or administrative proceeding.

Dated: December 4, 2006

s/Melissa L. Klipp
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